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FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. APPLICATION NO. FILING DATE 017534-000740US 2521 10/765,380 01/26/2004 Rodney A. Perkins **EXAMINER** 20350 12/29/2005 TOWNSEND AND TOWNSEND AND CREW, LLP MALLARI, PATRICIA C TWO EMBARCADERO CENTER PAPER NUMBER **ART UNIT EIGHTH FLOOR** SAN FRANCISCO, CA 94111-3834 3736

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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|  | Application No.  | Applicant(s)   |  |  |  |
|--|--|----------------|--|--|--|
|  | 10/765,380   | PERKINS ET AL. |  |  |  |
| Office Action Summary  | Examiner   | Art Unit       |  |  |  |
|  | Patricia C. Mallari  | 3736           |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply   |  |                |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |  |                |  |  |  |
| Status   |  |                |  |  |  |
| 1) Responsive to communication(s) filed on 03 Oc   | ctober 2005.   |                |  |  |  |
|  | <u>_</u>   |                |  |  |  |
| <u>'=</u>  | 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is |                |  |  |  |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  |  |                |  |  |  |
| Disposition of Claims  |  |                |  |  |  |
| <ul> <li>4)  Claim(s) 1-4 is/are pending in the application.</li> <li>4a) Of the above claim(s) is/are withdrawn from consideration.</li> <li>5)  Claim(s) is/are allowed.</li> <li>6)  Claim(s) 1-4 is/are rejected.</li> <li>7)  Claim(s) is/are objected to.</li> <li>8)  Claim(s) are subject to restriction and/or election requirement.</li> </ul>   |  |                |  |  |  |
| Application Papers   |  |                |  |  |  |
| 9) The specification is objected to by the Examiner.  10) The drawing(s) filed on 26 January 2004 is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  |  |                |  |  |  |
| Priority under 35 U.S.C. § 119   |  |                |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>   |  |                |  |  |  |
| Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  Paper No(s)/Mail Date   | 4)  Interview Summary<br>Paper No(s)/Mail Da<br>5)  Notice of Informal P<br>6)  Other:                             |                |  |  |  |

#### **DETAILED ACTION**

This is a final Office action. No new rejection has been presented.

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by US

Patent No. 5,588,424 to Insler et al. Insler discloses a system comprising an
isolation/access catheter having a proximal end, a distal end, an occlusion element 18
near the distal end, and at least one lumen 12, 14 extending therethrough (fig. 3; col. 3,
lines 14-38 of Insler). A sealing catheter 16 has a proximal end, a distal end, and a
closure element 32 releasably carried by the sealing catheter (fig. 3; col. 3, line 65-col.
4, line 6 of Insler). The sealing catheter 16 may be introduced though the lumen 14 of
the isolation/access catheter and the closure element may be deployed form the sealing
catheter 16 (fig. 3; col. 3, line 65-col. 4, line 13 of Insler).

As to the language "for performing intraluminal lung volume reduction" on lines 1-2 of the preamble, the applicants should note that this is merely intended use language which cannot be relied upon to define over the prior art, as Insler teaches all of the claimed elements and their recited relationships. See Ex parte Masham 1647 2 USPQ

2<sup>nd</sup> and MPEP §2111.02. The system of Insler appears to be fully capable of being used for performing intraluminal lung volume reduction.

Regarding claim 2, the closure element 32 comprises a swellable plug (col. 3, line 67; fig. 3 of Insler).

Regarding claims 3 and 4, the isolation/access catheter includes at least two lumens 12, 14 extending therethrough (fig. 3; col. 3, lines 14-30 of Insler). With further regard to claim 4, the isolation/access catheter further includes a fiberoptic bronchoscope disposed to permit forward viewing, wherein a fiberoptic bronchoscope necessarily comprises a fiber optic scope and a light source (col. 4, lines 5-9 of Insler).

### Response to Arguments

Applicant's arguments filed 10/3/05 have been fully considered but they are not persuasive.

In contending that Insler does not read on claim 1 of the instant application, the applicants merely state that they do not "believe that balloon 32 of Insler would in fact constitute a closure element as required by the present invention" and further state that "by requiring that the closure element to be releasable . . . it is clear that the balloon 32 of Insler cannot be considered to anticipate a read on the closure element of claim 1". However, as shown in figure 4 of Insler, balloon 32 is certainly capable of closing off or occluding the airway of the bronchus (col. 4, lines 8-13 of Insler) and therefore is shown being use as a "closure element" as recited in claim 1. As to the phrase "releasably carried" on lines 6 of claim 1, the term releasably or releasable merely indicates being

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capable of being released or set free. While the release of two items may require great force or destruction, any two connected items are still capable of being released or set free from each other. Clearly, the balloon 32 of Insler is clearly "releasably carried" by the sealing catheter 16. Therefore, the rejection of claims 1-4 under 35 U.S.C. 102(b) as being anticipated by Insler stands.

#### Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Mallari
Patent Examiner
Art Unit 3736

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